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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,023

06/27/2008

Vidya Narayan Acharya

11336.1022USWO

4735

52835

7590

01/14/2009

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EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

01/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,023	Applicant(s) ACHARYA ET AL.	
	Examiner Michael V. Meller	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,9-11,14,16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8, 12, 13, 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/29/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-13 and 15, chronic recurrent urinary tract infections, renal disorder due to bacterial infections, antibacterial therapy, that the standardized extract is standardized by bioassay in the reply filed on 12/12/2008 is acknowledged. The traversal is on the ground(s) that the art does not teach a standardized extract of *Tinospora cordifolia*. This is not found persuasive because as is evidenced herein a standardized extract of *Tinospora cordifolia* is known (see De Souza, abstract). Thus, a lack of unity does exist.
2. Thus, claims 5, 6, 9-11, 14, 16, 17 are withdrawn from further consideration as being drawn to non-elected subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by De Souza et al. (US 2002/0142055).

De Souza teaches that an extract of *Tinospora cordifolia* is standardized by bioassay. It is administered to humans, see abstract, example 5, paragraphs 1, 27-28, 31, 38-40, 44-50, 54, 60, the claims. It is also taught that the extract is administered along with conventional therapy, see example 5. Since the claim only requires that the extract be administered to “mammal”, then the mammal does not have to have a renal disorder and it does not then matter what causes the infection (disorder).

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 7, 8, 12, 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Upadhyay et al. in view of De Souza et al.

Upadhyay teaches that *Tinospora sp.* has been widely used in traditional Indian medicine for treatment of urinary tract infections, see col. 2, lines 25-40.

Upadhyay does not explicitly teach that *Tinospora cordifolia* is used to treat urinary tract infections or that the urinary tract infections are "chronic recurrent", that an antibacterial agent such as amoxicillin is used along with the extract, or that the extracts are standardized by bioassay.

De Souza teaches that an extract of *Tinospora cordifolia* is standardized by bioassay. It is administered to humans, see abstract, example 5, paragraphs 1, 27-28, 31, 38-40, 44-50, 54, 60, the claims. It is also taught that the extract is administered along with conventional therapy such as penicillins, see paragraph 48 and example 5.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to standardize the extract of *Tinospora cordifolia* of Upadhyay since De Souza makes it clear that *Tinospora cordifolia* is routinely standardized by bioassay. Further, De Souza teaches a bioassay which evaluates the bioactivity by determining the percentage of phagocytosis over a base line, wherein the percentage of phagocytosis is not less than 20 % over a base value, see paragraph 44.

Also Upadhyay teaches that plants of the *Tinospora* species have been widely used in traditional Indian medicine for treatment of urinary tract infections which would include using *Tinospora cordifolia* since *Tinospora cordifolia* was just mentioned a few lines above that as a preferred plant in the genus of *Tinospora*. Clearly one of ordinary skill in the art would have contemplated *Tinospora cordifolia* as one of the species in the *Tinospora* genus to be used for the treatment of urinary tract infections. Further, it clearly would have been within the purview of the ordinary artisan to use the extract for chronic recurrent urinary tract infections since the extract is already noted to be used for urinary tract infections and thus to use the extract for chronic recurrent urinary tract infections is obvious since knowing that the extract is widely used in Indian medicine for urinary tract infections it would also be obvious to use the extract for chronic recurring infections since these type of infections are chronic many times and do reoccur. To use an antibacterial such as amoxicillin is obvious since it is noted in De Souza to use penicillins as conventional therapy with the extract and to use a

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well known penicillin such as amoxicillin is well within the purview of the ordinary artisan since amoxicillin is one of the well known penicillins.

Since De souza does teach using antibacterials to treat the infection, then inherently the E. Coli and Klebsiella infections will be treated as well.

7. Claims 1-4, 7, 8, 12, 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Upadhyay et al. in view of De Souza et al. and further in view of Solanki.

Upadhyay teaches that *Tinospora sp.* has been widely used in traditional Indian medicine for treatment of urinary tract infections, see col. 2, lines 25-40.

Upadhyay does not explicitly teach that *Tinospora cordifolia* is used to treat urinary tract infections or that the urinary tract infections are "chronic recurrent", that an antibacterial agent such as amoxicillin is used along with the extract, or that the extracts are standardized by bioassay.

De Souza teaches that an extract of *Tinospora cordifolia* is standardized by bioassay. It is administered to humans, see abstract, example 5, paragraphs 1,

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27-28, 31, 38-40, 44-50, 54, 60, the claims. It is also taught that the extract is administered along with conventional therapy such as penicillins, see paragraph 48 and example 5.

Solanki teaches that *Tinospora cordifolia* is used to treat a patient who has renal failure and that using the extract helped the kidneys in filtering excess proteins and calcium, see paragraphs 3, 24-25, the claims and abstract, table 1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to standardize the extract of *Tinospora cordifolia* of Upadhyay since De Souza makes it clear that *Tinospora cordifolia* is routinely standardized by bioassay. Further, De Souza teaches a bioassay which evaluates the bioactivity by determining the percentage of phagocytosis over a base line, wherein the percentage of phagocytosis is not less than 20 % over a base value, see paragraph 44.

Also Upadhyay teaches that plants of the *Tinospora* species have been widely used in traditional Indian medicine for treatment of urinary tract infections which would include using *Tinospora cordifolia* since *Tinospora cordifolia* was just mentioned a few lines above that as a preferred plant in the genus of *Tinospora*. Clearly one of ordinary skill in the art would have contemplated *Tinospora cordifolia* as one of the species in the *Tinospora* genus to be used for the treatment of urinary tract infections. Further, it clearly would have been within the purview of the ordinary artisan to use the extract for chronic recurrent urinary

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tract infections since the extract is already noted to be used for urinary tract infections and thus to use the extract for chronic recurrent urinary tract infections is obvious since knowing that the extract is widely used in Indian medicine for urinary tract infections it would also be obvious to use the extract for chronic recurring infections since these type of infections are chronic many times and do reoccur. To use an antibacterial such as amoxicillin is obvious since it is noted in De Souza to use penicillins as conventional therapy with the extract and to use a well known penicillin such as amoxicillin is well within the purview of the ordinary artisan since amoxicillin is one of the well known penicillins.

Since Solanki teaches that *Tinospora cordifolia* is used to treat a patient who has renal failure and that using the extract helped the kidneys in filtering excess proteins and calcium this only further supports the argument that the claimed extract, *Tinospora cordifolia* does in fact treat urinary tract infections successfully since as noted by Solanki the kidneys were aided in filtering excess proteins and calcium which definitely helps in treating renal disorders such as chronic recurrent urinary tract infections.

Since De Souza does teach using antibacterials to treat the infection, then inherently the *E. Coli* and *Klebsiella* infections will be treated as well.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/
Primary Examiner, Art Unit 1655